

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO,

Plaintiff and Counterdefendant,

vs.

Cause No.: CIV 99-577 JC/WWD

GALEN D. KNIGHT, an individual;
and TERENCE J. SCALLEN, an individual;

Defendants and Counterplaintiffs.

DEFENDANT KNIGHT'S FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. Introduction

Based on the Court's Rulings (*Docs.* 191 and 226) the remaining Counts are I, III, V, VI (Knight), and VII. Plaintiff has stated in the Pretrial Order and the Pretrial Conference that it will not pursue Counts V, VI, and VII at trial. Plaintiff also stated in the Pretrial Conference on March 30, 2001, that Counts involving "Trade Secrets" were dropped, which Senior Judge John E. Conway confirmed. Plaintiff's Complaint, even as amended (Doc. 246), includes "Trade Secret" allegations in the General Allegations, and in Counts I, II, and VII. Plaintiff has since refused to drop all Counts as indicated to the Court and has even refused to drop the issue of "Trade Secrets", as Plaintiff stated in Court that it would by a Rule 41 Motion.

Failure of UNM to formally and timely drop Counts or issues as indicated and confirmed by the Court, forces Knight and Scallen to submit an extensive Defendants' Exhibit List and protracted Findings of Fact and Conclusions of Law. UNM also failed to provide Defendants an Exhibit List on or before the 4th of June, 2001, Defendant's combined Exhibit List being attached to Certificate of Service filed June 4, 2001 [Doc. 277] with corrections and supplemental Exhibits being filed June 8, 2001, by Knight.

If the "Trade Secrets" and other Counts are dropped as stated by both Plaintiff and the Court, then only Count III remains for consideration by this Court, Defendant's Counterclaims and Judgements on Counts II and IV being reserved by Defendant's for Appeal. If the Court decides to let UNM renege upon its stated and Court recognized obligation to drop the "Trade Secret" Counts, then Counts I and III may remain for consideration by this Court, the other Counts and Counterclaims upon which Judgment has been rendered being reserved for Appeal. If the Court decides to allow UNM to renege upon all of its obligations to drop the Counts as stated in Court, then Knight will ask for aggressive sanctions against UNM and ask that the Court Amend its Judgment on Counts II and IV and those Counts in the Defendants' Counterclaims, particularly those in Knight's Amended Countercomplaint concerning the Sherman Antitrust Act, SLAPPs, and other violations of State and Federal Law by UNM.

Such sanctions and Amendment of previous rulings appear Justified due to the recent discovery that UNM returned most if not all of these technologies by assignment to the Federal Government on January 29, 1998, which became effective April 6, 1998, well before this lawsuit was filed (Scallen's Findings of Fact and Conclusions of Law, Exhibit 1). Under these conditions, as defined by the Special Master, UNM appears to have abandoned or "assigned" away any possible ownership rights without giving the true inventors an opportunity to develop the technologies as provided in its 1983 Patent Policy, and UNM has NO right to file suit against the true inventors to enforce any ownership rights, equitable or otherwise. This continued lawsuit by UNM against the true inventors is frivolous and a violation of new State law derived from HB 241. UNM should not be allowed to abuse the Federal Agencies and the Federal Courts to renege upon its contractual obligations to the true inventors and to launder intellectual property in a manner that does not appear to be far removed from the laundering of money from the illicit activities by organized crime.

A. Count III

Regarding **Count III**, the following statements are relevant:

In the Pretrial Order (page 4, D. 1.) **Plaintiff** states:

"In Count III, a declaration that Defendants Knight and Scallen are the only joint and properly named inventors of the Vitaletheine Issued Patents is sought."

In the Pretrial Order (page 5, a.) **Knight** states:

"That Knight and Scallen be declared the only, joint and properly named inventors of the Vitaletheine Issued Patents and of any patents or applications deriving therefrom, and containing much the same compounds and utilities;"

In the Pretrial Order (page 9, paragraph 3) **Scallen** states:

"With regard to **Count III** the Court has already declared (*Doc.* 191, Order 9) that Knight and Scallen are the only and properly named Inventors of U.S. Patent 5,370,868, vitaletheine modulators in neoplasia. Scallen seeks an extension of that order by the Court to include U.S. Patent 5,578,313, U.S. Patent 6,096,536, and related patents and applications derived therefrom."

It is clear from the above statements that all three Parties are in agreement as to Count III.

Therefore, to the extent that the obviously false, unilateral amendments by UNM and its licensee can be corrected, or failing that the patents and applications containing false information abandoned, Knight is willing to stipulate that Knight and Scallen are the only true and properly named inventors of:

- a) the Vitaletheine Issued Patents (U.S. Patents 5,370,868, 5,578,313, and 6,096,536);
- b) the three 1992 vitaletheine modulator CIP patent applications (07/941926, 07/910892, and 07/928725; and
- c) any patents or applications deriving therefrom and containing much the same compounds and utilities.

B. Count I

Regarding **Count I** the Court has indicated that ownership of the vitaletheine modulator patents and patent applications will be determined after consideration of the issues concerning the insertion by amendment of new matter *three years* after the filing of the 1992 CIP vitaletheine modulator applications. [Clearly, the CIPs themselves by definition contained "new matter" when they were filed in 1992; this new matter was the

result of the substantial new experimental work by the Inventors following the filing of the original 1990 Applications.]

II. Findings of Fact

Historical

1. 1983-1986—vitaltheine modulator inventions conceived and reduced to practice by Knight and Scallen. Invention Disclosure for the vitaltheine modulator technologies made in a letter to Dean Napolitano on October 31, 1986, that also included information about the beta-aetheine discoveries.
2. 1983 University Patent Policy claims initial ownership by UNM of the Knight and Scallen Inventions.
3. May 16, 1989—UNM-CoInventor Agreement signed by Dean Leonard Napolitano.
4. July 6, 1990—three U.S. Patent Applications filed on the vitaltheine modulators.
5. May 1991—separate Assignments for each of the three 1990 vitaltheine modulator patent applications by the Inventors, Knight and Scallen, to UNM.
6. September 5, 1991—UNM Co-Inventor Agreement signed by Dean Leonard Napolitano.
7. July/August/September 1992—three CIP Applications concerning the vitaltheine modulators were submitted to USPTO with the knowledge and consent of the Inventors, Knight and Scallen. The Combined Declaration and Power of Attorney documents were signed by Knight and Scallen. No assignments were requested by UNM.
8. November 1, 1994—Back-to-back Papers issued in the prestigious scientific Journal, Cancer Research
9. November 11, 1994—Knight returned from AACR meeting in Taipei, Taiwan and stopped overnight in Denver to make a trip to Boulder to tour the Hauser facility, give a briefing on the

technology, and let Drs. Daughenbaugh, Taub, and Murray copy data on authentic compounds.

This is the only time Knight was in the Hauser facility.

10. December 6, 1994—based on one of these CIP Application U.S. Patent 5,370,868, *Vitaletheine Modulators in Neoplasia*, issued.
11. September 1994—new attorneys, without Power of Attorney from the true Inventors, assumed the patent prosecution of these applications.
12. Late 1994 through 1996—the University's and its licensee's agents (Christopher Murray, Hauser Chemical; and Shield Wallace, PAI) attempted to synthesize the vitaletheine modulators, failing to precisely follow the method of synthesis taught in U.S. Patent 5,370,868, in the Cancer Research Articles, and in the corresponding 1992 PCT Patent.
13. The resulting compounds differed substantially from the authentic vitaletheine modulators taught in U.S. Patent 5,370,868 when analyzed by a variety of techniques for chemical characterization, e.g., elemental analyses, infrared (IR) spectra, and mass spectra.
14. Neither UNM nor the licensee (Dovetail Technologies, Inc.) have provided evidence that these compounds as substituted by UNM and its licensee have any biological activity whatsoever.
15. 1995-1996—prosecution by those without power of attorney from the true inventors resulted in amendments to the applications that were submitted to USPTO by UNM and its licensee without the knowledge or consent of the Inventors, falsely changing the structures of the active compounds included in the 1992 CIP Applications and taught in U.S. Patent 5,370,868.
16. 1996-1997—after learning of the unauthorized substitution of incorrect structures into the patent applications, Knight and Scallen strenuously protested to UNM, the patent attorneys involved in patent prosecution, and to USPTO.

17. May 22, 1996—Ms. Annabelle Quintana, University patent administrator, submitted to USPTO a document claiming full right, title, and interest in the viteletheine modulator applications derived from the 1992 CIPs, even though assignment of these CIP applications by the Inventors had neither been sought in a timely fashion nor obtained as required by USPTO MPEP 306 .
18. November 26, 1996—U.S. Patent 5,578,313 issued, containing the incorrect structures that were blatantly substituted for the correct ones while still using the same experimental data obtained by Knight and Scallen using the correct structures (as reported in U.S. Patent 5,370,868). False changes to Table 1 by UNM and its licensee were so obvious that they were forced to correct these in patents issuing after US 5,578,313.
19. November 26, 1996—the only Inventor Declaration contained in U.S. Patent 5,578,313 was the same Inventor declaration signed by Knight and Scallen in 1992, swearing to the accuracy of the structures and experimental data included in the 1992 CIP application which resulted in U.S. Patent 5,370,868.
20. December, 1996—UNM patent administration office asks Knight and Scallen for assignments of the 1992 CIP Applications, the requested assignments having blanks with respect to royalty provisions, what was being assigned, or blatantly false statements, such as those concerning value of the technology and good and valuable consideration provided.
21. 1997—the Inventors protested [to Ms. Quintana, UNM patent administrator; Mr. Estes, UNM council; and USPTO] the erroneous nature of the structures contained in U.S. Patent 5,578,313, as well as the unauthorized, improper, and false changes made by UNM to Table 1 in this patent.
22. January 29, 1998—UNM **"assigned"** all three 1992 CIP viteletheine modulator applications and the resulting U.S. Patents (5,370,868 and 5,578,313) to the United States government, i.e., the

National Institutes of Health (NIH); UNM also assigned to NIH the two 1992 CIP beta-alethine applications and resulting U.S. Patent (5,643,966)!

[Scallen only very recently received evidence concerning this "assignment". These Abstracts of Title from USPTO are therefore attached his Findings of Fact and Conclusions of Law, Exhibit 1.]

23. May 21, 1999—UNM filed suit against Knight and Scallen, seeking assignments of the 1992 CIP Applications which UNM had already "assigned" to the National Institutes of Health in 1998.
24. August 1, 2000—U.S. Patent 6,096,536, purportedly derived from the 1992 CIP application 07/941926 *Vitaletheine Modulators in Cell Cultures and Therapy*, was issued, containing in it file wrapper the same unauthorized and incorrect structures for the vitaletheine modulators as contained in U.S. Patent 5,578,313. The only Inventor Declaration included in U.S. Patent 6,096,536 was that signed by Knight and Scallen in 1992 when the CIP application was filed.
25. 1996-present—based upon information provided and available it appears that all pending vitaletheine modulator applications, including *Vitaletheine Modulators in the Prophylaxis and Treatment of Disease*, have been abandoned, falsely amended by UNM (amendments which were unauthorized and contain incorrect structures for the vitaletheine modulators), or assigned to NIH.

Chemical Evidence

26. Knight has provided largely uncontested mass spectra evidence in the pleadings that the alleged structures of the vitaletheine modulators advocated by UNM are not present in the mass spectra of the authentic compounds obtained from Los Alamos National Laboratories and elsewhere [Doc. 239, Exhibit 2]. For example, the calcium salt of the authentic sulfenate-linked benzyl carbamate dimer has no evidence for a mass ion for the calcium salt of the alleged sulfonate, but there is a

- pronounced signal for the mass ion of the dihydrate of the calcium salt of the authentic sulfenate-linked benzyl carbamate dimer, a finding consistent with the true inventors' authentic structure.
27. Knight has provided largely uncontested IR evidence in the pleadings that the infrared (IR) spectra of the authentic compounds [Doc. 113, Exhibits 11,12 and Doc. 239, Exhibit 1] differ from those obtained by Dr. Murray in his alleged synthetic attempts to make the authentic compounds [Doc. 214, Exhibit 1,2,3,4,5]. See also [Doc. 26, Exhibits 2,3].
28. Dr. Wallace did not provide IR data for his alleged synthetic attempts and samples promised Knight for further analysis in exchange for his cooperation were not forthcoming, indicating intent to suppress. Their deficiency in NOT doing thorough analyses was pointed out in patent examination.
29. Knight has provided largely uncontested elemental analyses of the authentic compounds in the pleadings, which are virtually identical with that theoretically expected for the authentic compounds [Doc. 72, Exhibit 6], whereas the elemental analysis for Dr. Wallace's synthetic attempt at making the sulfenate-linked benzyl carbamate dimer differed from the expected values for the authentic compound by about 20% on average.
30. Knight has presented largely uncontested HPLC chromatography of derivatizations of authentic beta-alethine and vitalethine, before and after heating, in the pleadings to demonstrate dramatic differences in the chemistry of the two compounds [Doc. 254, Exhibits 3,4,5].
31. This largely uncontested chemical evidence corroborates the striking differences in biological potencies and activities of authentic compounds as reported in US 5,370,868, in the Cancer Research articles (11/1/94), and by many different laboratories and researchers, compared to the inferior potencies and activities of the compounds alleged by UNM and its licensee to be authentic. For example, vitaletheine treats allogeneic melanoma in the Cloudman S-91 model but an authentic preparation of beta-alethine was counterproductive at all dosages tested.

32. Arguments by UNM, its licensee, and their alleged Experts, that the authentic compounds used in the exemplary experiments were sulfonic acids, are impossible, since the authentic compounds were prepared under conditions that carefully controlled pH to preclude the possibility of damaging the structures with acid. These precautions admittedly were not taken in the alleged synthetic attempts of the alleged UNM's and its licensee's alleged Experts.
33. Dr. Murray, while lying repeatedly under oath to the patent office about the synthetic procedures and personnel used in the alleged attempts in his laboratory, admits in Hauser Report 4 that hydrobromic acid was dumped into an alleged attempt to reproduce an authentic structure, thereby departing from the authentic procedure in a way that apparently was designed to push the reaction toward the wrong (artifactual) compounds.
34. Dr. Wallace has written erroneous declarations under oath (filed in the USPTO by UNM and its licensee) that large ring structures, as reported for the authentic structure of vitaletheine V₄, cannot be formed or are unstable, apparently ignoring trade journals and scientific, peer-reviewed publications on crown ethers, the existence of even thiacycrown ethers being fairly common knowledge, now, in the trade Journals such as *Aldrichimica Acta*.
35. Dr. Wallace ignores the effects of hydrogen bonding in stabilizing large hydrogen-bonded structures, such as cyclic peptides used therapeutically (i.e., Sandostatin). Probable stabilization of the authentic structures with hydrogen bonding was illustrated in the Cancer Research articles (11/1/94).
36. By expressing an intent to use computer fabricated NMR data to support the false position of itself and its licensee, UNM will probably also ignore the effects of hydrogen bonding upon NMR data for the authentic compounds.
37. Knight has many e-mails between himself and scientists (and other administrative personnel) in a company that produces NMR resonance calculation packages. This company admits that their

software doesn't compensate for the effects of hydrogen bonding, resulting in NMR spectra that have doublets and triplets transposed in the estimated spectra of the starting material for the authentic compounds of the invention, the bis-N, N'-[CBZ-beta-alanyl]-cystamine.

38. Knight's solution for making the computer fabricated data more accurate was gratefully acknowledged by specialist in this company having technical expertise.
39. UNM, its licensee, and their alleged experts at various times and in various places have claimed three different chemical identities for authentic vitaethine, none of which were supported by chemical data on the authentic compounds.
40. UNM has denied the existence of carbamate/carbonimide and carbonimidic/carbamic acid structures [Doc. 92, Exhibit 2] even though there are a multitude of peer-reviewed scientific articles on the existence and characterization of these types of structures, some of which are quoted in the Cancer Research articles (11/1/94)[Doc. 113, Exhibit 7]. Included in the list of published scientists are about 11 who are living in or have resided in the Albuquerque area, such as UNM's own Phil Eaton and Nick Matwiyoff [Doc. 151, Exhibits 2,3].
41. UNM's denial of the vitaethine structure is further discredited by patents issuing worldwide on compounds or utilities for same having carbonate esters of beta-aethine (sic., vitaethine) in them. Drs. Taub, Daughenbaugh, and Murray [Doc. 109, Exhibits 2,3], the same persons holding interviews with the Examiners of patent applications naming Knight and Scallen as inventors to discredit and falsely amend Knight's and Scallen's authentic patent applications, are showing up as the alleged inventors of these apparently unenforceable patents and applications that misjoinder and non-joinder the true inventors [Doc. 72, Exhibits 2, 3, 4, 5 and Doc. 121, Exhibits 3,4,5]
42. Taub, et al., apparently with UNM's blessing, have been substituting false structures and data on accurate patents and applications bearing Knight' and Scallen's names in an apparent attempt to fraudulently discredit the authentic works and inventorships [Doc. 26, Exhibits 1,2,3,4,5].

- 43 When the portion of the molecule in these patents and applications is beta-alethine, then carbonate esters of beta-alethine is just another way of saying vitaethine. This apparent violation of the doctrine of equivalents by UNM and its licensee is uncontested, so far, in this litigation.
44. Even without this interpretation of nomenclature for vitaethine, these alleged and unenforceable patents and applications claim the same utilities for using beta-alethine that are present in the earlier authentic Patents appropriately listing Knight, Mann, and Scallen as inventors.
45. In several instances there is evidence that prosecution of patents and applications (by UNM, its licensee, and attorneys hired by same) is being conducted without full disclosure of known prior art to the USPTO, thereby knowingly and intentionally violating patent law in an apparent attempt to defraud the true inventors out of their inventorships and inventions.
46. Knight requested in discovery that UNM identify any incorrect information on VitaleTherapeutics, Inc. web site. Since no such errors have been identified by UNM, one must presume the web site correct.
47. As the file wrapper for 6,096,536 illustrates, the Examiner was reluctant to accept UNM's and its licensee's false amendments to the structures. The Examiner apparently persisted in this denial of the false amendments until the person or persons representing the licensee lied to the Examiner, stating falsely that they represented the true inventors' scientific positions. This situation was verbally confirmed by the Examiner in a telephone conversation with Knight.
48. All of this evidence, presented by the true inventors, stands in stark contrast to the paucity of information and evidence presented by UNM and its licensee that supports any legitimate efforts on their part to reproduce any of the authentic compounds.
49. Hauser Report 4 contains a mass spectra, allegedly of beta-alethine, that indicates the product of their attempt to synthesize this compound is much too large by about 80 mass units (Exhibit 1, Dr. Murray's Declaration, Doc. 70) to be authentic. Error in the mass spectrometer is usually 1 mass

unit or less, so this represents a horrendous discrepancy that can most easily be explained by an atom of bromine being artifactually and chemically bonded to the beta-alethine structure.

50. When confronted with this fallacy, Dr. Murray produced another mass spectra of the “new and improved” beta-alethine, which had been concealed from the true inventors previously. This mass spectra shows what appears to be a contaminating mixed disulfide of beta-alethine and cysteamine (Exhibit 2, Dr. Murray’s Declaration, Doc. 70), an artifact that at the concentrations being used by the licensee could cause single strand breaks in DNA.
51. From provisional applications filed by Drs. Taub, Murray, and Daughenbaugh and others, Knight has deduced a third artifact, the result of using yet another modified procedure for attempting to make authentic vitaethine. By using acetone instead of acetonitrile to precipitate and/or recrystallize the beta-alethine building block, the licensee (sic., Taub, et al.) has the potential for making Schiff’s bases between the acetone and any beta-alethine produced.
52. This artifact would be a structural analogue of the carbonimide/carbonimidic acid tautomer of authentic vitaethine, and could very well be an extremely potent inhibitor of the beneficial biological activities of vitaethine. Taub, et al., report biological activities for their alleged authentic preparation of beta-alethine [Doc. 177, Exhibits 1,3] that are tens of thousands of times less potent than the authentic beta-alethine preparations [Doc. 177, Exhibits 2,4], albeit in different assays.
53. Still, in several species and biological assays, the optimum doses of authentic beta-alethine preparations are the same within about one order of magnitude (instead of 8 or 9), humans and mice responding in virtually the same way to the authentic preparations. The only conclusion that can be drawn from this is that UNM and its licensee are not producing the authentic preparation of beta-alethine [Doc. 177, Exhibits 2,4].
54. Taub, et al., claim to be removing the counterproductive component from beta-alethine through their modified procedure, but the potency of their preparation appears to be far inferior instead of

superior to the authentic beta-alethine, making it more likely that they've removed an active ingredient or contaminated the preparation with something that poisons the biological activity.

55. Vitaethine is probably 100 million to 3 billion times more potent than authentic beta-alethine and has been shown to be chemically different from authentic beta-alethine with regards to carbon NMR [Doc. 114, Exhibits 14,15, 16], proton NMR [Doc. 113, Exhibits 8,9], mass spectra [Doc. 113, Exhibit 17], IR [¶27, supra, and HPLC [¶30, supra].
56. Taub, et al., have misrepresented facts about the biological activities of beta-alethine in melanoma models, essentially lying about peer-reviewed scientific papers in the US patent office [Doc. 177, Exhibit 5] and in their own scientific paper and web site [Doc. 65, Exhibit H and Doc. 196, Exhibits 3,4].
56. UNM has violated numerous state and federal laws in its apparent attempt to assist its licensee, as identified in the Pretrial Order [Doc. 274], including violations of the Sherman Antitrust Act [Docs. 136,137] and Constitutional Rights by SLAPP [Docs. 238, 239].

III. Conclusions of Law

A. New Matter

1. Insertion of New Matter Invalidates Patents.

The chemical structures of the vitaetheine modulator compounds as lawfully exemplified in the 1994 U.S. Patent 5,370,868 must be considered presumptively correct (35 U.S.C. 282). 35 U.S.C. 282, "Presumption of validity; defenses", states in pertinent part:

"A patent shall be presumed valid."

U.S. Patent 5,370,868, issued December 6, 1994, contains the correct and authentic structures for the vitaetheine modulators and is presumed valid under 35 U.S.C. 282. This Patent was supported by an oath or declaration from each of the Inventors (Knight and Scallen), and was prosecuted by attorneys having Power of Attorney from Knight and Scallen.

U.S. Patents 5,578,313, 6,096,536, and all pending applications concerning the vitaletheine modulators, containing substituted, incorrect structures (i.e., different from those taught in U.S. Patent 5,370,868) are invalid based upon 35 U.S.C. 132 which states in pertinent part:

"No amendment shall introduce new matter into the disclosure of the invention."

As Plaintiff has pointed out in the Pretrial Order (page 23), "if new matter is introduced during the prosecution of a patent application, claims depending on or incorporating such new matter are invalid under 35 U.S.C. 112, ¶ 1. Waldmar Link, GmbH & Co. v. Osteonics Corp., 32 F.2d 556, 558, 31 U.S.P.Q.2d 1855 (Fed. Cir. 1994); Transco Prod., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 558, 32 U.S.P.Q.2d 1077 (Fed. Cir. 1994); Texas Instr., Inc. v. Int'l Trade Comm'n., 871 F.2d 1054, 1065, 10 U.S.P.Q.2d 1257 (Fed. Cir. 1989); In re Rasmussen, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981); SDS USA, Inc. v. Ken Specialties, Inc., 122 F.Supp.2d 533, 544 (D.N.J. 2000)."

37 CFR 1.67(c) states in pertinent part:

"A supplemental oath or declaration meeting the requirements of 1.63 must also be filed if the application was altered after the oath or declaration was signed"

It is uncontested that the *only* Inventor Oath or Declaration in each of the above referenced Patents and Patent Applications was signed in 1992, *prior* to the introduction of the amendments introducing substituted incorrect structures (new matter) in 1995-1996. Thus, a supplemental oath or declaration was mandatory under 37 CFR 1.67(c), but for obvious reasons was neither sought nor obtained by UNM from Knight and Scallen. Patent or application altered after signing by Inventors by adding to specification and adding three claims is invalid as violating patent office rules of practice. Carter-Wallace, Inc. v. United States (1974) 204 Ct Cl 341, 496 F.2d 535, 182 USPQ 172. Therefore, U.S. Patents 5,578,313, 6,096,536, and all amended vitaletheine modulator applications are *invalid*, due to changes in the specification and claims. This invalidity is true for any changes inserted by UNM or its licensee subsequent to the Inventor Oath or Declaration signed in 1992, and *does not require the addition of new matter*. UNM simply failed to observe

the requirements for a Supplemental Declaration under 37 CFR 1.67(c) and, therefore, UNM failed to conform to Patent Laws and Regulations.

It is impossible for *both* U.S. Patent 5,370,868 and 5,578,313 to be valid, since they contain the same experimental data purportedly showing the same biological activity for two distinct and structurally very different sets of compounds. Only the patent claiming use of structures compounds that were actually used in these experiments can be valid. That patent is U.S. Patent 5,370,868.

There can be **no basis** for the *presumption of correctness* for the *substituted* structures, proposed by others, who **i)** were not Inventors, **ii)** who changed the method of synthesis, and **iii)** who apparently did not adequately compare the biological activities of the alleged compounds (sulfonates, sulfonic acids, or taurines) which they synthesized by other methods with the biological activities obtained for the authentic vitaletheine modulators used by Knight and Scallen in all of their experiments.

2. Unlawful Patent Prosecution Invalidates Patents.

The invalidity of U.S. Patents 5,578,313, 6,096,536, and other applications containing the substituted structures is further supported by the illicit nature of the prosecution of these patents and patent applications. Knight and Scallen are the Inventors (Applicants) and also the owners of the 1992 CIP applications and their progeny, since UNM had neither sought nor obtained assignments *prior* to the insertion of amendments changing the structures of the vitaletheine modulators in 1995 through 1999.

USPTO MPEP 306 states in pertinent part:

"Substitute or continuation-in-part applications require a new assignment if they are to be issued to an assignee."

At the time UNM and its licensee first attempted to insert amendments into many of the CIP Applications, changing the structures of the vitaletheine modulators and introducing new matter, Knight and Scallen were the Applicants (owners) of these CIP applications, since the CIP assignments had neither been sought nor obtained by UNM. Under these circumstances UNM and its agents have no legal authority to pursue

patent prosecution independent of the Inventors (37 CFR 3.73). Further, from the Fall of 1994, the attorneys handling the patent prosecution had **NO** Power of Attorney from Knight and Scallen, the Inventors (Applicants and owners) of the 1992 CIP Applications.

Therefore, the amendments in question and the resulting amended Patents and Applications are invalid, due to lack of legal authority of UNM, its licensee and their agents to amend the 1992 CIP Applications in any way whatsoever, subsequent to the Fall of 1994 when the attorneys authorized by the Inventors were replaced by others falsely authorized by UNM and its licensee.

USPTO acceptance of the substituted structures was *improperly influenced* by **a)** the failure of the University to inform the Inventors, Knight and Scallen, of the substitutions (amendments) prior to submission (i.e., the University *concealed* this from Knight and Scallen), **b)** the failure by UNM to even seek Supplemental Declarations, **c)** the use by UNM of out-dated (1992) Inventor Declarations, and **d)** the false statements made by UNM, its licensee and/or their agents to the patent Examiners claiming inventor approval of the amendments changing the structures of the authentic vitaletheine modulators—all of which **deceived** the patent Examiners into believing that the Inventors approved of the false amendments. For example, the **only** Inventor Declarations included in the file-wrappers for U.S. Patents 5,578,313 and 6,096,536 were those signed in 1992, three to seven years **prior** to the submission of the amendments.

The United States Patent and Trademark Office (USPTO) was further *deceived* with regard to the authority of those submitting the amendments by the false claim of ownership submitted by the University patent administrator in May of 1996, who knew or should have known that Assignments of the 1992 CIP Applications had neither been sought nor obtained from the Inventors, Knight and Scallen.

The above actions and omissions by the University combined to **deceive** the USPTO into accepting the false amendments and issuing US Patents 5,578,313 and 6,096,536, and presumably into accepting false amendments of U.S. Patent Applications No. 08/463,784, 08/466,143 and 08/469,697. A decision by the United

States Patent and Trademark Office concerning these false amendments is **not** presumptively correct, nor is the issuance of patents presumptively correct when based upon invalid, incorrect and deceptive documents, and false representations concerning the Inventors' positions on the true structures and these amendments.

Clearly, the University, its license and their agents have violated 18 U.S.C. 1001.

Under these circumstances, a determination by the Patent and Trademark Office that an amendment does not introduce "new matter" as defined in 35 U.S.C. 132 is **not** entitled to "an especially weighty presumption of correctness." Brooktree Corporation v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574-75 (Fed Cir. 1993).

A party that does not have clear ownership cannot pursue patent prosecution without Power of Attorney and prior approval by the Inventors for all amendments, changes in specifications, or changes in claims. Neither UNM nor its licensee have clear ownership. Therefore, all Patents and Applications containing the false structures must be reissued or corrected to restore the authentic vitaletheine modulator structures.

F. Ownership

In Count I of the Complaint Plaintiff seeks a declaration of ownership for all of the Vitaletheine Modulator Patents and Patent Applications. This Count is based upon the claim of initial ownership in the 1983 University Patent Policy.

Section 2 of the 1983 UNM Patent Policy states:

"..., such inventions or discoveries belong to the University".

That this claim of ownership is actually a claim of *initial* ownership is made clear in section 5a of that Policy:

"In the case of any invention or discovery which *initially* belongs to the University under the provisions of section 2 above, ... ". [Emphasis supplied.]

If the University did own the Knight and Scallen Inventions by its claim of *initial* ownership, assignments would not have been necessary at any time, the warranties of ownership in 1994 and 1996 would

have been valid, and the suit in 1999 would be unnecessary, frivolous, moot, and actionable under Rule 11 of Fed. R. Civ. P. Further, if the claim of initial ownership by UNM in the 1983 Patent Policy is valid, the 1991 Assignments are null and void since one cannot assign/sell what one does not own.

If the claim of *initial* ownership in the 1983 Patent Policy is **not** valid (see below) and since there is no requirement for assignment or any other transfer language in the Patent Policy, the Inventors have never been under any obligation to assign their ownership.

Evidence for the invalidity of this claim of *initial ownership* by UNM in its 1983 Patent Policy is found in 35 U.S.C. 111, 261, and in Dubilier and its progeny. See below and *Docs.* 111 and 146.

Inventors are the initial owners of their Inventions.

Ms. Quintana, UNM patent administrator agrees; she states *(Quintana Declaration, ¶ 5, *Doc.* 70):

"The inherent presumption raised by these two sections (111 and 261) is that inventors own the inventions they create, unless they are otherwise contractually required to relinquish their rights to their employer or some other party." [Emphasis supplied.]

The 1983 University Patent Policy contains no provisions requiring Inventors to *relinquish* their rights or to assign their Inventions. Even UNM's Special Master Regan agrees (*Doc.* 205, page 21, B.):

"The 1983 Patent Policy does not expressly state that Defendants would 'assign' inventions to the University."

If an employee is not hired to invent and there is no contractual obligation to assign, then employee inventions belong to the Inventor. United States v. Dubilier Condenser Corp. (1933) 289 US 178, 77 L Ed 1114, 53 S. Ct. 554, 85 ALR 1488; U.S. Colloid Mill Corp. v. Myers (1934, DC NY) 6F Supp 283; American Cyanamid Co. v. Hubbell (1935), (CA3 NJ) 76 F2d 807, 25 USPQ 27; National Development Co. v. Regan (1956) 2 Misc 2d 455, 153 NYS2d 348, 157 NE2d 505; Photometric Products Corp. v. Radtke (DC NY) 104 USPQ 4; and Hewett v. Samsonite Corp. (1973) 32 Colo App 150, 507 P2d 1119.

Knight and Scallen were neither hired to invent nor were they under any contractual obligation to assign, Knight in particular. See Scallen Third Declaration, ¶¶ 1-8, *Doc.* 146. UNM refused to provide

Knight's entire set of employment files in discovery, since this would have illustrated lack of a contract between Knight and UNM.

In addition Universal Sales Corp. v. California Press Mfg. Co. (1942) 20 Cal 2d 751, 128 P.2d 665, 55 USPQ 107 demonstrates that **corporations cannot be the initial owners of Inventions**. The University is a "*body corporate*" under New Mexico law (21-7-4, NMSA 1978). Therefore, UNM's claim of *initial* ownership in the 1983 Patent Policy (sections 2 and 5a) is *invalid* and is, therefore, *not contractually binding on the Inventors*, Knight and Scallen. An invalid provision of a contract is not enforceable.

Knight has pointed out (*Doc.* 233, ¶¶ 6-16) that the 1983 Patent Policy claim of *initial* ownership *misrepresents* both Federal Patent Law (35 U.S.C. 111 and 261) and applicable case law, as referred to above. Therefore, because of this *misrepresentation* by UNM in the 1983 Patent Policy, the Inventors were deceived by UNM in negotiations of good and valuable consideration when asked or ordered to assign their Inventions to the University. [see Scallen Fourth Declaration, ¶ 7, *Doc.* 155]. This fact alone *invalidates* the five 1991 Assignments.

Regardless of the validity or invalidity of the claim of initial ownership in the 1983 Patent Policy and regardless of the validity or invalidity of the 1991 assignments, the warranty of ownership in the 1994 License Agreement by UNM and the claim of "full right title and interest" made by UNM's patent administrator (Ms. Quintana) to USPTO in May of 1996 are invalid. By USPTO definition (MPEP 201.08), CIP Applications include new, additional matter not included in the 1990 parent applications. The USPTO requires assignment of CIP applications if ownership is to be vested in anyone other than the Inventors, Knight and Scallen (MPEP 306).

The Inventors were never asked to assign the five 1992 CIP applications *prior* to UNM's giving false warranty of ownership on August 23, 1994. See Quintana [Second] Declaration, *Doc.* 54, ¶ 9, page 5.

Even if UNM claims that there is a contractual obligation to assign the 1992 CIPs, which there isn't, UNM should have asked for such assignment in 1992. Plaintiff admits that it did *not* request assignment at that

time. See Quintana Declaration*, Doc. 54, ¶ 9, page 5. UNM *knew, or should have known*, of this mistake. Accrual began in August/September of 1992. Accrual is **not** activated when one party discovers its mistake. City of Carlsbad v. Grace, 1998-NMCA-144, 126 N.M. 95, 966 P.2d 1178 (Ct. Ap. 1998).

If UNM considers failure to assign the 1992 CIPs to constitute a breach of contract, **Plaintiff should have asked for such assignments in 1992**, and should have filed suit against Knight and Scallen long before May of 1999, **almost seven years after** UNM claims it was entitled to assignment of the 1992 CIP applications. Therefore, any conceivable statute of limitations bars recovery by UNM for injunctive relief concerning Counts I, II, and IV. Therefore, such claims for injunctive relief, i.e., assignment, are **futile*.

Thus, assuming the structures can be corrected from the false amendments by UNM and its licensee, Knight and Scallen are the owners of the three 1992 Vitaletheine Modulator Patents and Patent Applications and their progeny, including U.S. Patents 5,370,868, 5,578,313, and 6,096,536; and other pending Vitaletheine Modulator Patent Applications. Otherwise, the falsely amended patents and applications are invalid.

G. Failure of Good and Valuable Consideration

Knight really doesn't want to be owner of this technology, but ownership is perceived as one of the few ways, under the circumstances, to definitively stop the unlawful prosecution and misrepresentation of scientific fact upon patents, applications for same, and other papers under his name without his approval or concurrence. This illicit activity is tantamount to the abuse of Knight's endorsement to further products that are, at least, far less effective than the authentic ones and potentially harmful. Knight refuses to assign any document that endorses scientific or other information known to be false. To do so would implicate Knight in the illicit activities of others and could even subject him to being the scapegoat for these unlawful activities of others. The "blank check assignments" (sic., endorsements) sought by UNM, aside, Knight had no choice but to reject requests for assignment once it became evident that data and structures were being falsified under Knight's and Scallen's name in the USPTO. If Knight had signed the requested endorsement of falsified information, Knight

would have had complicity in the fraud being perpetrated on the patent office by others, and might have been held solely responsible for the unlawful and fraudulent activities of others, since Knight's name was one of those on the applications being fraudulently amended.

Knight has repeatedly expressed an interest in developing the authentic technologies and has devoted a 7 year unpaid effort to improve the scientific accuracy, purity, and testing for the authentic vitaletheine modulators. Knight cannot endorse or be associated or affiliated with any effort that injects obviously impure or untried preparations into humans. Thus, the only compounds of interest to Knight are the authentic ones and various legitimate permutations of same as identified in authentic patents and applications. Decarboxylated compounds and those known in the prior art, as unlawfully and fraudulently substituted on patents and applications bearing Knight's name as an inventor, are of little interest to Knight and limited to those defined in the authentic patent applications. The artifacts promoted by UNM and its licensee are of concern as an inert media for conveying the more active authentic compounds in such a way that it is chemically difficult, but not impossible, to detect the infringement. Hence, reason for this litigious persecution of Knight, who has the knowledge and experience to detect patent infringement and fraud. This SLAPP suit is designed to prevent Knight from reporting infringement and fraud by UNM and its licensee to the appropriate agencies, as required by law.

The blacklisting of Knight from further employment for 7 years aside, UNM's prejudgment seizure of Knight's share of royalties and fees due him to use against him in Court, and failure of UNM to abide by terms of the UNM CoInventor agreements with regards to control of research and development and spokespersons for the authentic technologies are clearly outside the realm of lawful activity [Doc. 255]. Prejudgment seizure is "tantamount to nonpayment" [citing PPG Industries, Inc. v. Westwood Chemical, Inc. in Nebraska Engineering Corp. v. Shivvers, 557 F.2d 1257 (ith Cir. 07/14/1977)]. Even "the escrowing of royalty payments [sic., has] been characterized as an unjustified, prejudgment seizure of a licensor's property to secure a licensee's potential recovery . "[Milton Roy Co. v. Bausch Lomb, Inc., 418F. Supp. 975 (D.Del. 1976)]. Two

Supreme Court decisions reinforce this position: *Eastern Enterprises v. Apfel*, 118 S.Ct. 2131, 141 L.Ed.2d 451 (U.S. 06/25/1998) identifies even the taking of property through overregulation as seizure through eminent domain and requiring compensation; and the Supreme Court in *TXO Production Corp. v. Alliance Resources*, 1993. SCT.3938<<http://www.versuslaw.com>>, 113 S. Ct. 2711, 125 L.Ed.2d 366, 61 U.S.L.W. 4766 (6/25/1993) held that one cannot feign bad title or worthless quitclaim deed to renegotiate royalty arrangements.

UNM's abandonment of the originally assigned technology and its "assignment" and "license" to Dovetail Technologies and to the Federal Government exposes its true motive, to deny Knight and Scallen their inventorship and shares of royalties due them and to prevent Knight and Scallen from developing the authentic compounds under circumstances in which there is no credible evidence that UNM or its licensee have even made any of the authentic compounds or preparations in the past 7 years. This alone amounts to a loss of about a third of the time covered by a patent for developing the authentic compounds. Pharmaceutical grade compounds could have been made and clinical trials started in 1994, and, and indeed, definitive experiments were being performed with the authentic compounds when UNM shut the research laboratories down in February of 1994, in the middle of a 350 mouse melanoma study. Knight has since prepared even purer preparations with pharmaceutical grade reagents and has made these available for testing in veterinarian clinics.

Other than UNM's contention that Knight and Scallen are inventors upon the authentic patents and applications, virtually none of UNM's other Counts and allegations are true. Knight's Answer to Complaint and CounterComplaint (Doc.3) contains a few key Exhibits that, for the most part discredit UNM's allegations and Counts and help identify UNM's Complaint as a SLAPP [Docs. 238, 239, 257].

Knight has since found letters that further substantiate his position that UNM denied Knight control of research and development (UNM Co-Inventor Agreement) as early as February of 1994, and that soon after UNM also denied Knight a spokesperson's role in providing accurate information about the authentic compounds and utilities to Examiners in the USPTO and others. These breaches of contract by UNM occurred

long before any issue of “reassignment” arose. When UNM claimed the reason Knight was laid off was lack of funds, the hiring of Dr. Wallace at 6 times Knight’s salaried rate, underscores this intentional and malicious breach of contract by UNM. This was particularly grievous when Dr. Wallace failed to make authentic compounds or preparations in many instances and misrepresented the chemistry of the authentic compounds he did manage to make. Thus, UNM was in flagrant violation of its contractual obligations long before its manufactured and fabricated “failure and refusal to assign, deliver, and return” allegations. This is corroborated by the simple fact that UNM did not ask for “assignment or reassignment” until **after** it started surreptitiously cooperating with its licensee to falsify data and structures in the USPTO on the authentic patent applications naming Knight and Scallen as inventors. Ironically, this is about the same time (10/17/95) that UNM’s licensee filed its first provisional application that resulted in patents and applications claiming Taub, et al., as inventors on much the same compounds and utilities as the authentic inventions by Knight and Scallen.

VII. Summary

1. Assuming falsely amended patents and applications can be corrected and reissued where needed, Knight and Scallen are the only true and properly named inventors of the Vitaletheine Issued Patents (U.S. Patents 5,370,868, 5,578,313, and 6,096,536) and of any patents or applications deriving from the 1992 CIP applications, and containing much the same compounds and utilities.

2. U.S. Patents 5,578,313, 6,096,536, and all amended vitaletheine modulator applications that are not corrected are invalid based upon **either**:

- a) changes in the specification and claims inserted by UNM subsequent to the Inventor Oath or Declaration signed in 1992 by Knight and Scallen; or
- b) insertion of new matter into the specification by UNM; or
- c) unlawful patent prosecution by UNM without authorization from the Inventor (Applicant) owners, Knight and Scallen.

3. Assuming falsely amended patents and applications can be corrected and made valid, Knight and Scallen are the inventors and owners of:

- a) the Vitaletheine Issued Patents (U.S. Patents 5,370,868, 5,578,313, and 6,096,536);
- b) the three 1992 vitaletheine modulator CIP patent applications (07/941926, 07/910892, and 07/928725; and
- c) any patents or applications deriving therefrom and containing much the same compounds and utilities, such as the Canadian and international patents and applications.

Based upon the above "Findings of Fact and Conclusions of Law" Knight respectfully requests the Court find in favor of the Defendants on the above issues and Counts, including but not limited to those Counts determined to now be before the Court, and in so doing help move the authentic technology forward.

Respectfully Submitted,

Salim D. Knight

I hereby certify that a true and correct copy of the foregoing was faxed and mailed to the following on June 11, 2001:

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